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VALVULAR DISEASE

THE MITRACLIP® IN HIGH-RISK PATIENTS

The EVEREST II investigators have published the findings of their substudy assessing MitraClip® (Evalve, Menlo Park, CA, USA) use in symptomatic patients with severe or moderate-to-severe mitral regurgitation (MR) and at high risk of surgery-associated death. They believe the results "demonstrate that these patients, who were not considered to be suitable candidates for surgery, can be successfully treated with the MitraClip® system to reduce the degree of MR."

In the 75 high-risk patients who underwent MitraClip® implantation, 30-day and 1-year mortality were 7.7% and 24.4%, respectively. The investigators highlight that mortality was "significantly less than that predicted for open-heart mitral valve surgery" and "not different" to that of a comparator group ($n=36$) that received standard treatment (86% medical management, 14% surgery). Notably, the comparator group was recruited retrospectively (after the results of the MitraClip® cohort were known) from the pool of high-risk patients who had been screened, but not included, in the MitraClip® cohort.

In most of the patients who underwent MitraClip® implantation, MR and left ventricular volumes were reduced, and NYHA functional class and quality of life improved, at the 30-day and 1-year follow-ups.

In an accompanying editorial, Dr Zoltan Turi and Dr Michael Rosenbloom from Cooper University Hospital, NJ, USA agreed that the study was very important. However, they noted strong concerns about the comparator group, including that "more than 50% were screen failures and did not meet anatomic criteria, ... patients were selected retrospectively and included only a subset of those eligible, ... and no information [was] provided on patient management".

Drs Turi and Rosenbloom caution that "without PARTNER A- and B-like prospective randomized enrollment to MitraClip® versus medical therapy for patients who are at high risk (A) and truly inoperable (B), the benefits of MitraClip® therapy in these patients remain uncertain." They believe that whilst the results of the EVEREST II substudy indicate that the MitraClip® should continue to be available to high-risk patients at institutes with extensive experience, it should not be considered for routine use in these patients until we have solid findings from randomized, controlled trials.

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Original citation Whitlow, P. L. *et al*. Acute and 12-month results with catheter-based mitral valve leaflet repair: the EVEREST II (Endovascular Valve Edge-to-Edge Repair) high risk study. *J. Am. Coll. Cardiol*. **59**, 130–139 (2012)